American National Standard

ANSI/AAMI 2700-2-1: 2022

Medical devices and medical systems—Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2-1: Particular requirements for forensic data logging

AAMI
Advancing Safety in Health Technology

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Abstract: ANSI/AAMI 2700-2-1 is part of the AAMI 2700 family of standards to achieve safe integrated clinical environments (ICE) (ANSI/AAMI 2700-1). It was developed by the AAMI Interoperability Working Group (IOWG, SM-WG03) and is intended for use by medical device and platform manufacturers and system integrators. It provides requirements for the recording, storage, and playback of data to support safety, quality assurance, and forensic analysis for medical devices, applications, and platforms. This document supports safe and secure device interoperability by providing general functional, performance, security, and interoperability requirements of ICE data logging systems. It requires that logged data to be time-synchronized. Data may include patient waveform and parameters, images and video, configuration, settings, device capabilities of each ICE-connected device, and user and patient interactions with each device (e.g., button presses).

Keywords: data logging, forensic data logger, Integrated Clinical Environment, ICE, interoperability

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Association for the Advancement of Medical Instrumentation

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